

up to 40% w/w of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, gives an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

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E1 27. (Amended) The self-emulsifying preconcentrate of claim 26, wherein the carrier system contains 15 to 75% w/w of the hydrophobic component.

28. (Amended) The self-emulsifying preconcentrate of claim 26, wherein the carrier system contains up to 30% w/w of the hydrophilic component.

AD/ADK 29. (Amended) A storage-stable, self-emulsifying, and non-aqueous preconcentrate of at least one taxane in a composition consisting essentially of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, 1,2-propylene glycol, ethanol, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, gives an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

SUB
E2 30. (Amended) The preconcentrate of claim 29, wherein the hydrophilic component comprises 1,2-propylene glycol and ethanol.

34. (Amended) The preconcentrate of claim 29, wherein the preconcentrate also includes an inhibitor of P-glycoprotein transport system or an inhibitor of cytochrome P450 enzyme.

Sub 63 / 35. (Amended) The preconcentrate of claim 34, wherein the preconcentrate comprises grapefruit extract or a component thereof.

36. (Amended) The preconcentrate of claim 29, wherein the taxane is paclitaxel or docetaxel.

37. (Amended) A method of orally or parenterally administering a taxane to a subject in need of same comprising administering a dose of a storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane consisting essentially of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% w/w of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, gives an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

38. (Amended) The method of claim 37, wherein the taxane is solubilized in the preconcentrate.

Please add the following new claims:

39. (New) A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion comprising a taxane dissolved in a carrier system, which carrier system consists essentially of:

10 to 80% w/w of a hydrophobic component;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% w/w of a hydrophilic component.

40. (New) The preconcentrate of claim 39, wherein the preconcentrate forms a liquid having an average droplet size of at most 10 microns when mixed with water or simulated gastric fluid.

41. (New) The preconcentrate of claim 40, wherein a dose of the preconcentrate has a taxane bioavailability of 25 to 60% upon oral administration.

42. (New) The preconcentrate of claim 41, wherein at least a portion of the hydrophilic component consists of ethanol, such that the carrier system contains at least 6% w/w ethanol.

6% of 0% is 0%!

43. (New) The preconcentrate of claim 39, wherein the preconcentrate, when mixed with an aqueous medium and heated to 20-37° C, forms a liquid having an average droplet size of at most 10 microns.

44. (New) The preconcentrate of claim 43, wherein the preconcentrate, upon oral administration, forms a microemulsion *in situ* in the gastrointestinal tract.

45. (New) A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion comprising a taxane dissolved in a carrier system, which carrier system consists essentially of:

10 to 80% w/w of a hydrophobic component;

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E4 7 20 to 80% w/w of a surfactant component; and
up to 40% w/w of a hydrophilic component, at least a portion of which hydrophilic component consists of ethanol, such that the carrier system contains at least 6% w/w ethanol.

46. (New) The preconcentrate of claim 45, wherein the surfactant component consists of one or more surfactants selected from the group consisting of polyoxyethylene-sorbitan-fatty acid esters, polyoxyethylene fatty acid esters, α -tocopherol, α -tocopheryl polyethylene glycol succinate, α -tocopherol palmitate, α -tocopherol acetate, PEG glyceryl fatty acid esters, propylene glycol mono- or di-fatty acid esters, sorbitan fatty acid esters, polyoxyethylene-polyoxypropylene co-polymers, glycerol triacetate, monoglycerides, and acetylated monoglycerides.

47. (New) The preconcentrate of claim 46, wherein the preconcentrate forms a liquid having an average droplet size of at most 10 microns when mixed with water or simulated gastric fluid.

DB 48. (New) The preconcentrate of claim 47, wherein a dose of the preconcentrate has a taxane bioavailability of 25 to 60% upon oral administration.

49. (New) The preconcentrate of claim 45, wherein the preconcentrate, when mixed with an aqueous medium and heated to 20-37° C, forms a clear liquid having an average droplet size of at most 10 microns.

50. (New) The preconcentrate of claim 49, wherein the preconcentrate, upon oral administration, forms a microemulsion *in situ* in the gastrointestinal tract.

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E5 1 51. (New) A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion comprising a taxane dissolved in a carrier system, which carrier system consists essentially of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

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20 to 80% w/w of a surfactant component consisting of one or more surfactants selected from the group consisting of a polyoxyethylene-sorbitan-fatty acid ester, a polyoxyethylene fatty acid ester, a polyoxyethylene castor oil derivative, α -tocopherol, α -tocopheryl polyethylene glycol succinate, α -tocopherol palmitate, α -tocopherol acetate, a PEG glyceryl fatty acid ester, a propylene glycol mono- or di-fatty acid ester, a sorbitan fatty acid ester, a polyoxyethylene-polyoxypropylene co-polymer, glycerol triacetate, a monoglyceride, an acetylated monoglyceride, and combinations thereof; and up to 40% of a hydrophilic component, at least a portion of the hydrophilic component consisting of ethanol, such that the carrier system contains at least 6% w/w ethanol.

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52. (New) The preconcentrate of claim 51, wherein a dose of the preconcentrate has a taxane bioavailability of 25 to 60% upon oral administration.

53. (New) An injectable pharmaceutically acceptable composition consisting essentially of a storage-stable, self-emulsifying, and non-aqueous preconcentrate of at least one taxane in a composition consisting essentially of:

10 to 80% w/w of a hydrophobic component;

20 to 80% w/w of a surfactant component; and

up to 40% w/w of a hydrophilic component,

wherein (a) at least a portion of the hydrophilic component consists of ethanol, such that the composition contains at least 6% w/w ethanol, (b) the surfactant component of the composition consists of one or more non-ionic surfactants, or (c) both.